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IFS
INTERNAL FIXATION SYSTEMS

JUL 26 2006

5619 N.W. 74th Avenue, Miami, Florida 33166

Internal Fixation Systems, Inc.
510(k) Summary

Company Name:	Internal Fixation Systems, Inc. 5619 N.W. 74th Avenue Miami, Florida 33166
Contact Name:	Steve Hernandez 5619 N.W. 74th Avenue Miami, Florida 33166 Phone (305) 216-4766 Fax (305) 887-7340
Trade Name:	IFS Cannulated Bone Screw
Common Name:	Cannulated Bone Screw
Regulation Name:	Smooth or Threaded Metallic Bone Fixation Fastener
Regulation Number:	21 CFR 888.3040
Regulatory Class:	II
Device Product Code:	HWC

Substantially Equivalent Devices:	Manufacturer	Trade Name	510(k) Number
	Precimed, Inc.	Precimed Cannulated Screw System	K050754
	Nexa Orthopedics	Nexa Bone Screw System	K053394
	aap Implants, Inc.	aap Cannulated Screw	K990776
	Ortho-Pro LLC	Cannulated Bone Screws	K042310
	Vilex, Inc.	Vilex Cannulated Screws	K991151 K991197

Device Description: The IFS Cannulated Screw is a self-tapping, self-drilling screw

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with a cancellous thread that can be guided into position by guidewire placement. Partial or fully threaded screws are available in 3.0mm, 3.5mm, and 4.0mm thread diameters and 10mm to 75mm in length.

Intended Use: The intended use of the IFS Cannulated Bone Screw is for the treatment of bone fractures, such as fractures of the tarsals and metatarsals, and for metatarsals and phalangeal osteotomies and arthrodses of the hand and foot.

Item	*Internal Fixation Systems, Inc.*	*Precimed, Inc*
Product Name	IFS Cannulated Bone Screw	Precimed Cannulated Screw System
Use	Single Use	Single Use
Fixation Type	Screw	Screw
Material	316L	316L
Sizes	Various diameters and lengths for small bone fractures	Various diameters and lengths for small bone fractures
Indications for Use	The IFS Cannulated Bone Screw is indicated for use in the treatment of bone fractures, such as fractures of the tarsals and metatarsals, and for metatarsals and phalangeal osteotomies and arthrodses of the hand and foot.	The Precimed Cannulated Screw System is indicated for use in the treatment of bone fractures, such as fractures of the tarsals and metatarsals, and for metatarsals and phalangeal osteotomies and arthrodses of the hand and foot.

Technological Characteristics Comparison: The IFS Cannulated Bone Screws are substantially equivalent to the predicate devices with respect to design, material, and indications for use.

Sterilization Information: IFS Cannulated Bone Screws (devices) will be distributed non-sterile. The devices are sterilized by the end user per the AAMI Guidelines "Good Hospital Practice: Steam Sterilization and Sterility Assurance" and ANSI/AAMI/ISO 11737 guidelines to achieve the Sterility Assurance Level (SAL) of 10^{-6}.

Conclusion: There are no significant differences between the Precimed Cannulated Screw System and the other devices as listed in the Substantially Equivalent Devices. The IFS device and the predicate devices have similar design attributes, material, and intended use thus is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2006

Internal Fixation Systems, Inc.
% Mr. Steve Hernandez
President
5619 N.W. 74th Avenue
Miami, Florida 33166

Re: K061620
Trade/Device Name: IFS Cannulated Bone Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: June 6, 2006
Received: June 9, 2006

Dear Mr. Hernandez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

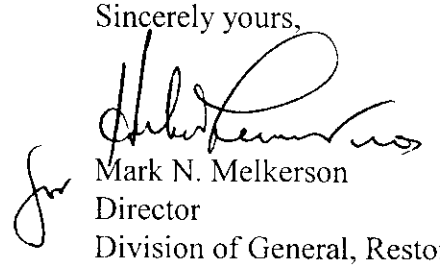
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: IFS Cannulated Bone Screw

Indications For Use: The Intended Use of the IFS Cannulated Bone Screw is for the treatment of bone fractures, such as fractures of the tarsals and metatarsals, and for metatarsals and phalangeal osteotomies and arthrodses of the hand and foot.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061620